

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-48 are pending in the present application. Claims 1-7, 11-14, 20-22, and 24-48 are withdrawn from consideration. No new claims are added. Claims 8-10, 15-19, and 23 are currently under examination.

The Invention

The present invention provides a family of dendrimers that are useful as, inter alia, supports, vectors, carriers or delivery vehicles for a variety of compounds in biomedical and technological applications. For example, the macromolecules may be used for the delivery of drugs, genetic material, imaging components or other functional molecules to which they can be conjugated. An additional feature of the macromolecules is their ability to be targeted to selected organs, tumors, or types of tissues.

Response to the Examiner's AGS comments

1) Thank you

As an initial matter, Applicants thank the Examiner for accepting the Alternative Grouping Scheme (AGS) and withdrawing the Second Restriction Requirement.

2) Applicants traverse the restriction of AGS Group II claims 11-14, 20-22, and 24-31.

On February 17, 2004, Applicants responded to Examiner Trinh's Second Restriction Requirement with a three page traversal, which included the AGS. One of the Groups in the AGS was Group II, claims 8-31. Applicants respectfully requested that i) the Examiner adopt the AGS and ii) if adopted, that the claims of Group II would be elected for prosecution.

In the Office Action dated May 24, 2004, Examiner Riley accepted the AGS proposal, and acknowledged Applicants' election of Group II, claims 8-31. In the same Office Action, the Examiner restricted the currently pending claims from 8-31 to 8-10, 15, 17-19, and 23. The Examiner then stated that Applicants did not point out the errors in the restriction

requirement, and treated the election as without traverse. Since Applicants actually did traverse Examiner Trinh's Second Restriction Requirement, and this is Applicants' first opportunity to respond to Examiner Riley's current restriction, Applicants request that the Examiner withdraw the 'without traverse' holding in this case.

Concerning Examiner Trinh's Second Restriction Requirement: In fact, Applicants traversed the Second Restriction Requirement. The traversal spanned three pages of Applicants' Response to the Second Restriction Requirement filed on February 17, 2004. Since a traversal was filed for this Restriction Requirement, Applicants respectfully request withdrawal of the 'without traverse' holding.

Concerning the restriction of Group II claims in the current Office Action: On May 24, 2004, Examiner Riley restricted the currently pending claims from 8-31 to 8-10, 15, 17-19, and 23. Since this is Applicants' first opportunity to respond to the May 24, 2004 Office Action, Applicants have not yet had the opportunity to respond to Examiner Riley's restriction of the pending claims. Therefore, Applicants respectfully request withdrawal of the 'without traverse' holding.

3) Traversal of the Restriction

Applicants respectfully traverse the current Restriction to claims 8-10, 15, 17-19, and 23 on the grounds that withdrawn claims 11-14, 16, 20-22, and 24-31 do not represent separate inventive entities from claims 8-10, 15, 17-19, and 23. This is because many of the withdrawn claims are in fact dependent upon the currently pending claims and thus cannot be considered separate entities. Applicants therefore respectfully request a search to be conducted that encompasses claims 11-14, 16, 20-22, and 24-31.

4) Requests for Rejoinder

If the Examiner does not grant Applicants' request, Applicants alternatively make two rejoinder requests. The first request is that, when the allowability of claim 8 is determined, that claims 11-14, 16, 20-22, and 24-31 be rejoined. Each of claims 11-14, 16, 20-22, and 24-31

is either directly or indirectly dependent upon claim 8, incorporating all of its elements. Thus, rejoinder of these claims is proper.

Applicants' second request is that, when the allowability of claim 8 is determined, that the claims of Group IV (claims 39-48) be rejoined pursuant to M.P.E.P. § 821.04. Claims 39-48 describe methods of making and using the dendrimers of the invention. Each of claims 39-48 are either directly or indirectly dependent upon claim 8, incorporating all of its elements. Thus, rejoinder of these claims is proper.

Responses to the Rejections

Under 35 U.S.C. § 102

To maintain a *prima facie* case of anticipation, the Examiner must demonstrate that each and every element as set forth in the claim is either expressly found or is inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the ...claim. See MPEP § 2131. Applicants submit that each element of the claims now pending has not been identified in the art presently of record. Therefore, Applicants respectfully traverse the following rejections.

Under 35 U.S.C. § 102(a)

Over Magnusson

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Magnusson, *et al.*, *Macromolecules*, **33**: 3099-3104 (2000) ("Magnusson"). Magnusson is cited by the Examiner for teaching a hyperbranched polymer from 2,2 bis(hydroxymethyl)propionic acid. Since Magnusson teaches a hyperbranched polymer, while Applicant teaches a dendrimer, an element of Applicants' invention is not present in Magnusson. Therefore, an anticipation rejection cannot be maintained.

Dendrimers and hyperbranched polymers refer to two different members of the family of dendritic, or highly branched, polymers. As noted in paragraphs 4-8 of the enclosed Declaration by Professor Jean Frechet, hyperbranched polymers have a degree of branching ("DB") of between 0.3 and 0.7, while dendrimers, on the other hand, have DB values that range

from 0.9 to 1.0. As noted by Professor Frechet, compounds with different DB values are different structurally as well. In paragraph 16 and 17 of his declaration, Professor Frechet notes that the polymers in Magnusson have DB values that are characteristic of hyperbranched polymers. Since Applicants claim dendrimers, while Magnusson teaches a structurally different compound (hyperbranched polymer), an element of Applicants' invention is not present in Magnusson. Therefore, the rejection over claims 8-10 and 15-19 is improper. Accordingly, Applicants respectfully request the withdrawal of this rejection.

Under 35 U.S.C. § 102(b)

Over Hult

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hult, *et al.*, (U.S. Pat. No. 5,418,301) ("Hult"). Hult is cited by the Examiner for teaching dendritic macromolecules where A is O, R⁵ and R⁶ are either H or a moiety comprising a reactive group. Since Hult's dendritic macromolecule is a hyperbranched polymer, while Applicants' dendritic macromolecule is a dendrimer, an element of Applicants' invention is not present in Hult. Therefore, an anticipation rejection cannot be maintained.

Dendrimers and hyperbranched polymers refer to two different members of the family of dendritic, or highly branched, polymers. As noted in paragraphs 4-8 of the enclosed Declaration by Professor Jean Frechet, hyperbranched polymers have a degree of branching ("DB") of between 0.3 and 0.7, while dendrimers, on the other hand, have DB values that range from 0.9 to 1.0. As noted by Professor Frechet, compounds with different DB values are different structurally as well. In paragraph 19-29, Professor Frechet notes that the polymers of Hult have DB values that are characteristic of hyperbranched polymers. Since the Applicants teach dendrimers, while Hult teaches a structurally different compound (hyperbranched polymer), an element of Applicants' invention is not present in Hult. Therefore, the rejection over claims 8-10 and 15-19 is improper. Applicants respectfully request the withdrawal of this rejection.

Over Trollas

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Trollas, *et al.*, *Macromolecules*, **31**: 3439-3445 (1998) ("Trollas"). Trollas is cited by the Examiner for teaching a dendrimer of the invention. However, as evidenced by the publication's title "Hyperbranched Poly(ϵ -caprolactone)s", Trollas teaches hyperbranched polymers instead of dendrimers. Since Applicants' molecules are dendrimers, while Trollas does not teach dendrimers, an element of Applicants' invention is not present in Trollas. Therefore, an anticipation rejection cannot be maintained.

Dendrimers and hyperbranched polymers refer to two different members of the family of dendritic, or highly branched, polymers. As noted in paragraphs 4-8 of the enclosed Declaration by Professor Jean Frechet, hyperbranched polymers have a degree of branching ("DB") of between 0.3 and 0.7, while dendrimers, on the other hand, have DB values that range from 0.9 to 1.0. As noted by Professor Frechet, compounds with different DB values are different structurally as well. In paragraphs 8-9, and 18, Professor Frechet notes that the polymers in Trollas have DB values that are characteristic of hyperbranched polymers. Since Applicant teaches dendrimers, while Trollas teaches a structurally different compound (hyperbranched polymer), an element of Applicants' invention is not present in Trollas. Therefore, the rejection over claims 8-10 and 15-19 is improper. Applicant respectfully requests the withdrawal of this rejection.

Under 35 U.S.C. § 103(a)

In order to establish a *prima facie* case of obviousness, the Examiner must demonstrate that (1) the references teach all the claimed elements; (2) there is a suggestion or motivation in the prior art to modify or combine the reference teachings; and (3) there is a reasonable expectation of success. MPEP § 2143; *In re Vaack*, 20 USPQ2d 1438 (Fed. Cir. 1991). As explained below, the references fail to disclose or suggest Applicants' claimed element of a dendrimer. Since the references do not contain this element, there is neither a suggestion to modify the reference teachings to produce Applicants' invention, nor a reasonable expectation of success derived from the references. Therefore, a *prima facie* case of obviousness

has not been put forth for claims 8-10 and 15-19 and Applicant respectfully traverses this rejection.

Over Magnusson

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Magnusson. The teachings of Magnusson is discussed above.

(1) Magnusson fails to teach all of the claimed elements

Magnusson fails to teach Applicants' claimed element of a dendrimer. As mentioned above and in the declaration by Prof. Frechet, Magnusson is directed to a type of dendritic polymer (hyperbranched polymer) that is structurally different from Applicants' disclosed dendrimers. Therefore, this element is missing from Magnusson. Since Magnusson fails to teach all of the claimed elements of Applicants' invention, a *prima facie* obviousness rejection cannot be maintained.

(2) There is no suggestion or motivation to modify or combine the reference teachings

The cited reference also fails to suggest a reason to modify a hyperbranched polymer in order to produce a dendrimer. As mentioned above, Magnusson discloses hyperbranched polymers, but contains no discussion of dendrimers. Since Applicants' invention involves dendrimers, and Magnusson does not contain any reference to dendrimers, there is no motivation to modify Magnusson in order to achieve the purpose of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

(3) The cited reference does not provide a reasonable expectation of success

The cited reference also fails to provide a reasonable expectation of success in performing the Applicants' invention. As mentioned earlier, there is nothing in Magnusson that suggests that a dendrimer can be produced from its disclosed hyperbranched polymer methods. Since the compositions of the claimed invention are dendrimers, and Magnusson does not contain a reference to dendrimers, then Magnusson cannot create a reasonable expectation that its methods can be successfully used to produce a compound of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

Because the cited reference fails to teach all the claimed elements, does not contain a suggestion or motivation to modify the reference teachings, and does not provide a reasonable expectation of success, a *prima facie* case of obviousness cannot be set forth. Thus, Applicant respectfully requests the withdrawal of the rejection.

Over Hult

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hult. Hult is described above.

(1) Hult fails to teach all of the claimed elements

Hult fails to teach Applicants' claimed element of a dendrimer. As mentioned above and in the declaration by Prof. Frechet, Hult is directed to a type of dendritic polymer (hyperbranched polymer) that is structurally different from Applicants' disclosed dendrimers. Therefore, this element is missing from Hult. Since Hult fails to teach all of the claimed elements of Applicants' invention, a *prima facie* obviousness rejection cannot be maintained.

(2) There is no suggestion or motivation to modify or combine the reference teachings

The cited reference also fails to suggest a reason to modify a hyperbranched polymer in order to produce a dendrimer. As mentioned above, Hult discloses hyperbranched polymers, but does not contain an enabling discussion of dendrimers. Since Applicants' invention involves dendrimers, and Hult does not enable the use of dendrimers, there is no motivation to modify Hult in order to achieve the purpose of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

(3) The cited reference does not provide a reasonable expectation of success

The cited reference also fails to provide a reasonable expectation of success in performing the Applicants' invention. As mentioned earlier, there is nothing in Hult that suggests that a dendrimer can be produced from its disclosed methods. Since the compositions of the claimed invention are dendrimers, and Hult does not contain an enabling reference to dendrimers, then Hult does not create a reasonable expectation that its methods can be

successfully used to produce a compound of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

Because the cited reference fails to teach all the claimed elements, does not contain a suggestion or motivation to modify the reference teachings, and does not provide a reasonable expectation of success, a *prima facie* case of obviousness cannot be set forth. Thus, Applicant respectfully requests the withdrawal of the rejection.

Over Trollas

Claims 8-10 and 15-19 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Trollas. Trollas is described above.

(1) Trollas fails to teach all of the claimed elements

Trollas fails to teach Applicants' claimed element of a dendrimer. As mentioned above and in the declaration by Professor Frechet, Trollas is directed to a type of dendritic polymer (hyperbranched polymer) that is structurally different from Applicants' disclosed dendrimers. Therefore, this element is missing from Trollas. Since Trollas fails to teach all of the claimed elements of Applicants' invention, a *prima facie* obviousness rejection cannot be maintained.

(2) There is no suggestion or motivation to modify or combine the reference teachings

The cited reference also fails to suggest a reason to modify a hyperbranched polymer in order to produce a dendrimer. As mentioned above, Trollas discloses hyperbranched polymers, but contains no discussion of dendrimers. Since Applicants' invention involves dendrimers, and Trollas does not contain any reference to dendrimers, there is no motivation to modify Trollas in order to achieve the purpose of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

(3) The cited reference does not provide a reasonable expectation of success

The cited reference also fails to provide a reasonable expectation of success in performing the Applicants' invention. As mentioned earlier, there is nothing in Trollas that suggests that a dendrimer can be produced from its disclosed hyperbranched polymer methods.

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PATENT

Since the compositions of the claimed invention are dendrimers, and Trollsas does not contain a reference to dendrimers, then Trollsas cannot create a reasonable expectation that its methods can be successfully used to produce a compound of Applicants' invention. Therefore, the *prima facie* obviousness rejection cannot be maintained.

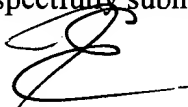
Because the cited reference fails to teach all the claimed elements, does not contain a suggestion or motivation to modify the reference teachings, and does not provide a reasonable expectation of success, a *prima facie* case of obviousness cannot be set forth. Thus, Applicant respectfully requests the withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1000.

Respectfully submitted,



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